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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,473	04/08/2004	Wei Chen	900.1009US	1056
23280 7590 10/19/2007 DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			EXAMINER SOROUSH, ALI	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,473	<b>Applicant(s)</b> CHEN ET AL.	
	<b>Examiner</b> Ali Soroush	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 54-60 and 62-113 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-60 and 62-113 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgement of Receipt***

Applicant's response filed on 07/30/2007 to the Office Action mailed on 01/25/2007 is acknowledged.

### ***Status of the Claims***

Claims 1-53 and 61 have been cancelled, claims 54, 58-60, and 62 have been amended, and claims 63-113 have been newly added. Therefore claims 54-60 and 62-113 are currently pending examination for patentability.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. The rejection of claims 61 and 62 are under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in light of the amendment filed with the aforementioned response.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 54-57 under 35 U.S.C. 102(b) as being anticipated by Jancso et al. (British Journal of Pharmaceutical Chemotherapy, pp. 138-151, Published 1967) **is maintained**.

***Response to Applicants Arguments***

Applicant argues that a naturally extracted capsaicin would not have a purity of about 97% or greater. In fact the applicant argues that the prior art extracted capsaicin has only about 69% capsaicin. Examiner concedes that the prior art does not teach a capsaicin of about 97% purity, however claims 54-57 as filed with the aforementioned response are not limited by the amount of purity. With regard to the trans capsaicin being synthetic, this does not impart a patentable limitation. The properties of capsaicin compound are not different because the compound is synthesized rather than naturally acquired. For the foregoing reasons the rejection of claims 54-57 under 35 U.S.C. 102(b) is maintained.

2. The rejection of claims 58-60 under 35 U.S.C. 102(b) as being anticipated by Jancso et al. (British Journal of Pharmaceutical Chemotherapy, pp. 138-151, Published 1967) **is withdrawn** in light of the amendment filed with aforementioned response.

3. Claims 54-60 and 63-113 is rejected under 35 U.S.C. 102(b) as being anticipated by Limlomwongse et al. (Journal of Nutrition, pp. 773-777, Published 05/1979) as evidenced by Jancso et al. (British Journal of Pharmaceutical Chemotherapy, pp. 138-151, Published 1967).

Limlomwongse et al. teaches delivery of varying doses of pure synthetic capsaicin, in saline solution, into the lumen of rat via a gastric fistula. (See abstract).

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Jancso et al. defines capsaicin as trans-N[4'-hydroxy-3'-methoxy-benzyl]-8-methylnon-6-enamide. With regard to the amount of purity claimed in claims 58-60 these would necessarily be taught by Limlomongse et al. because Limlomongse et al. teaches the capsaicin is synthetically derived and pure therefore it would be approximately 100% trans-capsaicin. It is noted that the recitation of the intended use "treatment of nociceptive pain, neuroceptive pain, pain from nerve injury, pain from neuralgia ..." (claim 55) and "treatment of orthopedic disorders selected from ..." (claim 56) has not been given patentable weight to distinguish over **Limlomwongse et al.** because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since **Limlomongse et al.** discloses compounds that are the same as those claimed, they would be capable of performing the intended use, as claimed. Therefore, the reference is deemed to anticipate the instant claims above. In a claim to a composition a statement to the composition's intended use has no patentable weight since the intended use does not structurally change or add component(s) to the composition. With regard to limitations in claims 54 and 63-113 related to the process by which capsaicin is prepared, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

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from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Circ. 1985)" (See MPEP 2113). For the foregoing reasons the instant invention is anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. The rejection of claim 62 under 35 U.S.C. 103(a) as being unpatentable over Jancso et al. (British Journal of Pharmaceutical Chemotherapy, pp. 138-151, Published 1967) in view of Guenzler-Pukall et al. (US 2004/0204356 A1, Published 10/14/2004) **is maintained.**

### ***Response to Applicants Arguments***

Applicant argues that a naturally extracted capsaicin would not have a purity of about 97% or greater. In fact the applicant argues that the prior art extracted capsaicin has only about 69% capsaicin. Examiner concedes that the prior art does not teach a capsaicin of about 97% purity, however claims 54-57 as filed with the aforementioned response are not limited by the amount of purity. With regard to the trans capsaicin being synthetic, this does not impart a patentable limitation. The properties of capsaicin compound are not different because the compound is synthesized rather than naturally acquired. For the foregoing reasons the rejection of claim 62 under 35 U.S.C. 103 is maintained.

2. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Limlomwongse et al. (Journal of Nutrition, pp. 773-777, Published 05/1979) in view of Guenzler-Pukall et al. (US 2004/0204356 A1, Published 10/14/2004).

***Applicant Claims***

A pharmaceutical composition comprising trans-capsaicin comprising about 99% or greater trans-capsaicin and vehicle suitable for injection wherein the vehicle comprises about 20% PEG 300, about 10 mM histidine and about 5% sucrose in water.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Limlomwongse et al. is disclosed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Limlomwongse et al. does not expressly teach using a pharmaceutical vehicle comprising polyethylene glycol (PEG 300), histidine, and sucrose. Teachings of Guenzler-Pukall et al. cure this deficiency.

Guenzler-Pukall et al. teaches, "**Suitable carriers for intravenous injection of the invention is well known in the art and include water-based solutions containing a base, such as, for example sodium hydroxide, to form an ionized compound, sucrose or sodium chloride as tonicity agent, for example, the buffer contains phosphate or histidine. Co-solvents, such as, for example, polyethylene glycols, maybe added.** These water-based systems are effective at dissolving the compound of the invention and produce low toxicity upon systemic administration. The proportions of a solution system may be varied considerably, without destroying solubility and toxicity characteristics." (See page 13, paragraph 0137).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***



It would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to incorporate various conventional pharmaceutical carriers (vehicles) such as PEG's, histidine, and sucrose within the injectable compositions taught by Limomwongse et al. based on the beneficial teachings provided by Guenzler-Pukall et al. which discloses that such conventional carrier (vehicles) are suitable therefor. The adjustment of particular conditions (e.g. determining appropriate amount ranges of carriers including PEG, histidine, and sucrose therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For the foregoing reasons given the instantly claimed invention is made obvious.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
SABIHA QAZI, PH.D.  
PRIMARY EXAMINER